DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1615-FN]

Medicare Program; Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the request from Lake Pointe Medical Center for an exception to the prohibition against expansion of facility capacity.

DATES: EFFECTIVE DATE: This notice is effective on [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT:

Patricia Taft, (410) 786-4561 or Teresa Walden, (410) 786-3755.

SUPPLEMENTARY INFORMATION:

I. Background

Unless the requirements of an applicable exception are satisfied, section 1877 of the Social Security Act (the Act), also known as the physician self-referral law -- (1) prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation); and (2) prohibits the entity from filing claims with Medicare (or billing any individual, third party payer, or other entity) for those DHS furnished as a result of a prohibited referral. Section 1877(d)(3) of the Act provides an exception, known as

the “whole hospital exception,” for physician ownership or investment interests held in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital). Section 1877(d)(2) of the Act provides an exception for physician ownership or investment interests in rural providers (the “rural provider exception”). In order for an entity to qualify for the rural provider exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the DHS furnished by the entity must be furnished to individuals residing in a rural area.

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (hereafter referred to together as “the Affordable Care Act”) amended the whole hospital and rural provider exceptions to the physician self-referral prohibition to impose additional restrictions on physician ownership and investment in hospitals and rural providers. Since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding facility capacity unless it qualifies as an “applicable hospital” or “high Medicaid facility” (as defined in sections 1877(i)(3)(E), (F) of the Act and 42 CFR 411.362(c)(2), (3) of our regulations) and has been granted an exception to the facility expansion prohibition by the Secretary. Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with respect to the provider’s application for the exception. Section 1877(i)(3)(H) of the Act states that the Secretary shall publish in the Federal Register the final decision with respect to an application for an exception to the prohibition against facility expansion not later than 60 days after receiving a complete application.

For further information on the physician-owned hospital expansion exception process, visit our website at: http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.

II. Exception Approval Process

On November 30, 2011, we published a final rule in the **Federal Register** (76 FR 74122, 74517 through 74525) that, among other things, finalized §411.362(c), which specified the process for submitting, commenting on, and reviewing a request for an exception to the prohibition on expansion of facility capacity. We specified that prior to our review of the request, we will solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register** (see §411.362(c)(5)). We also stated that individuals and entities in the hospital's community have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an "applicable hospital" or "high Medicaid facility," as such terms are defined in §411.362(c)(2) and (3). Although we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health care programs, we noted that these were examples only and that we would not restrict the type of community input that may be submitted (76 FR 74522). If we receive timely comments from the community, we will notify the hospital, and the hospital has 30 days after such notice to submit a rebuttal statement (§411.362(c)(5)(ii)).

A request for an exception to the facility expansion prohibition is considered complete and ready for CMS review if no comments from the community are received by the close of the

30-day comment period. If we receive timely comments from the community, we consider the request to be complete 30 days after the hospital is notified of the comments. If we grant the request for an exception to the prohibition on expansion of facility capacity, the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§411.362(c)(6)). Our decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity will be published in the **Federal Register** in accordance with our regulations at §411.362(c)(7).

III. Public Response to Notice with Comment Period

On May 12, 2014, we published a notice in the **Federal Register** (79 FR 26969) entitled, Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition. In the May 12, 2014 notice we stated that as permitted by section 1877(i)(3) of the Act and our regulations at §411.362(c), the following physician-owned hospital requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Lake Pointe Medical Center

Location: 6800 Scenic Drive, Rowlett, Texas 75088-4552 (Rockwall County)

Basis for Exception Request: High Medicaid Facility.

In the May 12, 2014 notice we also solicited comments from individuals and entities in the community in which Lake Pointe Medical Center is located. Eighty-four comments were submitted under docket number for the notice (CMS-2014-0061). Eighty-three of those comments advocated that a different physician-owned hospital in another county be allowed to

expand under the expansion exception process. Those comments were not relevant to the Lake Pointe Medical Center request, and we have not considered them in deciding the request. The only remaining comment urged CMS to evaluate whether Lake Pointe Medical Center is a "high Medicaid facility" using data that our regulations do not permit us to consider.

On August 4, 2014, as required by §411.362(c)(5)(ii), we notified Lake Pointe Medical Center that we received comments in response to the May 12, 2014 notice and that these comments were available for public viewing at http://www.regulations.gov. Lake Pointe Medical Center submitted a rebuttal statement on August 13, 2014. The statement indicated that the comments raised no issues of law or fact that in any way contradict Lake Pointe Medical Center's assertion that it meets all of the statutory and regulatory requirements to qualify as a high Medicaid facility. On September 3, 2014, at the close of the 30-day rebuttal period, CMS deemed the request complete pursuant to §411.362(c)(5)(ii).

IV. Decision

This final notice announces our decision to approve the request from Lake Pointe Medical Center for an exception to the prohibition against expansion of facility capacity. As set forth in our current regulations and public guidance documents, Lake Pointe Medical Center submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as a high Medicaid facility. Further, our regulations do not permit us to consider the data recommended by the one relevant comment. Therefore, in accordance with section 1877(i)(3) of the Act, we have granted the request from Lake Pointe Medical Center for an exception to the expansion of facility capacity prohibition based on the following criteria:

- The hospital is not the sole hospital in Rockwall, Texas, the county in which it is located;

- The hospital certified that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; and

- With respect to each of the 3 most recent fiscal years for which data were available as of the date the hospital submitted its request, the hospital has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in Rockwall County, Texas, the county in which the hospital is located.

Our approval grants the request of Lake Pointe Medical Center to add a total of 36 beds. Pursuant to §411.362(c)(6), the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds. Lake Pointe Medical Center certified that its baseline number of operating rooms, procedure rooms, and beds for which it was licensed as of March 23, 2010, was 129. Accordingly, we find that granting the additional 36 beds will not result in an aggregate number of operating rooms, procedure rooms, and beds for which the hospital is licensed that exceeds 200 percent of the hospital's baseline.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C.35).

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Dated: October 22, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

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